CLERK'S OFFICE U.S. DIST. COURT AT ROANOKE, VA FILED

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IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF VIRGINIA ROANOKE DIVISION

MAR 13 2006 JOHN F. CORCORAN, CLERK

LIFELINE AMBULANCE SERVICE, INC.,	<i>'</i>
,	Civil Action No. 7:02-cv-1026
Plaintiff,)
)
v.) <u>MEMORANDUM OPINION</u>
)
MICHAEL O. LEAVITT,)
Secretary of Health and Human Services,)
) By: James C. Turk
Defendant.) Senior United States District Judge

Plaintiff Lifeline Ambulance Service, Inc., (Lifeline) brings this action against defendant Michael O. Leavitt, Secretary of Health and Human Services, seeking judicial review of defendant's final agency decision denying additional Medicare reimbursement of certain ambulance services supplied to Medicare beneficiaries by Lifeline during the period of March through August, 1997. Lifeline has exhausted its administrative remedies and the parties have fully briefed the issues in this case. This matter is before the court on cross motions for summary judgment pursuant to Federal Rule of Civil Procedure 56. Upon review of the parties' pleadings and the administrative record, the court finds that the agency's interpretation of its own regulations is not plainly erroneous or inconsistent with the language of its regulations or the Medicare statutes; therefore the court must defer to the agency's decision in this action.

Accordingly, the court will grant defendant's motion for summary judgment and deny plaintiff's motion for summary judgment.

I.

The facts in this case as contained in the pleadings and the administrative record (A.R.) are as follows. Lifeline avers it is a licensed Medicare Part B certified ambulance supplier of medical

services in Virginia.¹ Specifically, Lifeline supplies emergency medical, basic life support (BLS), advance life support (ALS), and specialized life support (SLS)² services to residents including Medicare beneficiaries. Lifeline has accepted all rights to Medicare beneficiaries' benefits from the beneficiaries at issue in this action. Lifeline challenges certain federal statutes, regulations, and guidelines as interpreted and applied by the defendant. Lifeline contends that the defendant, through the Health Care Financing Administration (HCFA) (now known as the Centers for Medicare & Medicaid Reimbursement (CMS)) and its private contractors improperly denied certain Medicare claims for additional reimbursement submitted by Lifeline for providing SLS ambulance services.

From March through August, 1997, Lifeline provided SLS ambulance services to 139

Medicare beneficiaries. Lifeline submitted claims for ALS services provided to beneficiaries and was reimbursed from Medicare. Lifeline then submitted claims under the Physician's Current Procedural Terminology (CPT) code A0999³ to the Secretary's Medicare contractor (the "carrier") for additional reimbursement beyond the ALS rate for extra personnel, training, and use

¹Medicare Part B is a voluntary supplementary insurance program covering physicians' services and certain other medical and health services that includes ambulance services where necessary due to the beneficiary's medical condition at the time of transport, "but only to the extent provided in regulations." 42 U.S.C. § 1395x(s)(7); see 42 C.F.R. § 410.40-41.

²SLS ambulance service is defined as "a sophisticated and specialized level of prehospital and interfacility emergency care which includes basic and advanced services which could be described as Neonatal life support, pediatric life support, or adult life support." A.R. 310.

³Code A0999 is an unlisted procedure code for ambulance services that is used when no specific code is assigned. A.R. 204, 219, 225-26. Lifeline calculated the total of its claims for SLS services by "multiplying the 139 claims by the usual and customary charge of \$300 per claim, and then multiplying again by 80%, the amount Medicare will reimburse." Pl.s Mem. Supp. Mot. Summ. J., 4.

of new technology for SLS services in the total amount of \$33,360; Lifeline alleges it did so under the advice of the carrier, who then improperly denied these claims. The carrier denied the claims on grounds that the HCFA recognizes only BLS and ALS ambulance services, and no separate payment may be made to Lifeline for its SLS services because the ALS rate includes SLS services. A.R. 1254. The carrier reasoned that "it is the prevailing practice of ALS providers to bill an *all-inclusive* base rate [] [which] includes *all services* provided by the ambulance crew. Therefore, Medicare's allowed charge for ALS includes extra personnel, training and use of new technology" for SLS services. <u>Id.</u>

In accordance with Medicare administrative review procedures, Lifeline appealed the carrier's decision to a hearing officer who upheld the carrier's decision under the Supplemental Medical Insurance benefit provisions of Title XVIII of the Social Security Act, 42 U.S.C. § 1395, et seq. (the "Act"). A.R. 225. The hearing officer reasoned that,

[t]he Medicare carrier is charged with the responsibility of determining those items and services covered under the Medicare program, as well as the Medicare allowable amounts for those items and services. Regulations set out the procedures to be followed in doing so. These procedures are reviewed periodically by the [] [HCFA], an agency of the Federal Government, to ensure that the proper processes have been followed, and that they are consistent with the law, regulations and guidelines.

A careful review of the testimony, taped telephone conversation between Ms. Bonnie Hockaday, exhibits in the file and the medical records establishes that procedure code A-0999 is an unlisted procedure code for ambulance services used by the carrier when a specific code has not been assigned for the service provided. The [] [HFCA] recognizes two levels of ambulance service [– BLS and ALS]. In Virginia, it is the prevailing practice of ALS providers to bill an all-inclusive base rate. This includes all services provided by the ambulance crew. Therefore, Medicare's allowed charge for ALS includes extra personnel, training and use of new technology. The hearing officer believes that the services were reasonable and necessary but has no authority to change the carriers policy.

<u>Id.</u> at 225-26.⁴

Lifeline appealed the hearing officer's decision to an administrative law judge (ALJ) who affirmed the hearing officer's denial of Lifeline's claims. The ALJ held that the Act, regulations, and Medicare Carriers Manual (Manual) "provide no vehicle for additional reimbursement for the SLS services provided to the beneficiaries [and] [a]ccordingly, there is no reimbursement under Part B of Title XVIII of the [] Act for the specialized life support services provided to the beneficiaries and billed under procedure code A0999." Id. at 52; compare 42 C.F.R. 410.40(a) (1997) (providing a general definition of ambulance services); and 42 C.F.R. 410.40(b) (1999) (providing distinctions between BLS and ALS services); with 42 C.F.R. 410.40(b), 414.605 (2004) (providing further distinctions between BLS and ALS services and two different types of ALS services, but failing to address SLS services). Additionally, the ALJ held, inter alia, that although Lifeline's services were "reasonable and necessary" the SLS services "were included in the all-inclusive base rate used by the Provider and other ground ambulance providers in [] Virginia." Id. at 53. Furthermore, to support her findings the ALJ cited to the Manual § 5116.1B, stating that "separate additional charges may be permitted for a specialized ALS service so long as the 'total reasonable charge allowed [] does not exceed the all-inclusive prevailing base rate for ALS services,' thereby implying that there may be no additional charges for specialized ALS service tacked onto the all-inclusive prevailing base rate." Id. at 52. Additionally, the ALJ further concluded under the Manual §§ 5024, 5200, that,

⁴Lifeline filed two separate but identical complaints to the hearing officer concerning the 139 claims. Thus, the hearing officer's factual findings and decisions for both complaints were identical; and the ALJ's factual findings and decisions for both complaints were identical. A.R. 215-27, 50-64.

charges higher than customary or prevailing charges may be paid under certain conditions, such as unusual circumstances or medical complications, and when it is acceptable medical service practice in the locality to make an extra charge in such instances. See MCM §§ 5024, 5200. Ambulance services are not one of the examples cited, but, more importantly, the Provider has not shown the requisite unusual circumstances or medical complications involved and that it is the practice in the locality to make an extra charge. Indeed, the Medicare Fair Hearing Officer noted that "[i]n Virginia, it is the prevailing practice of ALS providers to bill an all-inclusive base rate" including "all services provided by the ambulance crew."

Id.; see also id. at 61.

Lifeline then requested that the Medicare Appeals Council review the ALJ's decision; the Appeals Council rejected Lifeline's request and concluded that pursuant to Medicare regulations there was no basis for granting its request. The Appeals Council cited four instances under the regulations where requests for review would be granted: (1) there appears to be an abuse of discretion by the ALJ; (2) there is an error of law; (3) the ALJ's action, findings, or conclusions are not supported by substantial evidence; or (4) there is a broad policy or procedural issue that may affect the general public interest. Id. at 1. The Appeals Council held that Lifeline failed to establish any of these instances. Id. The Appeals Council reasoned that "[t]he regulations also provide that where new and material evidence is submitted with the request for review, the entire record will be evaluated and review will be granted where the Council finds that the [] [ALJ's] action, findings, or conclusion is contrary to the weight of evidence currently of record." Id. (citing, 20 C.F.R. 404.970 and the notices published in the Federal Register on December 13, 1995 (60 FR 64065) and May 12, 1997 (62 FR 25844, 25849)). Upon considering the plaintiff's brief and reviewing the administrative record, the Appeals Council additionally concluded "that

there is no basis under the above regulations for granting the request for review." Id.

Therefore, the ALJ's decision stands as the final decision of the Secretary and Lifeline properly exhausted administrative remedies prior to filing this action. Lifeline alleges that at each level of review the administrative reviewers and the Appeals Council misapplied the law and ignored substantial evidence in the record. Lifeline maintains that the Secretary's decision is "arbitrary, capricious, an abuse of discretion, otherwise not in accordance with law; is not supported by substantial evidence; and is in excess of statutory authority or short of statutory right." Pl.'s Mem. Supp. Mot. Summ. J., 3. Lifeline argues that under Medicare regulations its claims for additional reimbursement should have been granted because (1) it demonstrated unusual circumstances based upon the requirements imposed by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (the "Act"), the Emergency Medical Treatment Act and Active Labor Act (EMTALA), and Virginia state law, and (2) because the SLS services and costs were reasonable and necessary based upon the patients' medical conditions to warrant reimbursement for additional services under the regulations.

The defendant responds that Lifeline's claims were properly denied in the administrative review process under the agency's regulations because it failed to meet the requirements for Medicare reimbursement in excess of the all-inclusive base rate, and the local practice in Virginia is to charge only the all-inclusive base rate.

H.

Upon motion for summary judgment, the Court must view the facts, and inferences to be

⁵Lifeline filed this action in the United States District Court for the District of Columbia; that court transferred the case to this court.

drawn from those facts, in the light most favorable to the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986); Nguyen v. CNA Corp., 44 F.3d 234, 236-7 (4th Cir. 1995). Summary judgment is proper where there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. However, "[t]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986).

When a motion for summary judgment is made and properly supported by affidavits, depositions, or answers to interrogatories, the non-moving party may not rest on the mere allegations or denials of the pleadings. Fed. R. Civ. P. 56. Instead, the non-moving party must respond by affidavits or otherwise present specific facts showing that there is a genuine issue of disputed fact for trial. <u>Id.</u> If the non-moving party fails to show a genuine issue of fact, summary judgment, if appropriate, may be entered against the non-moving party. <u>See Celotex Corp. v.</u> Catrett, 477 U.S. 317, 322 (1986).

III.

Upon review of the Secretary's Medicare reimbursement decision, judicial review must be narrow and deferential where the Secretary's factual findings are supported by substantial evidence, as defined by that which "a reasonable mind might accept as adequate to support a conclusion." Consolo v. Federal Maritime Commission, 383 U.S. 607, 619-20 (1966), (quoting, Consolidated Edison Co. of New York v. NLRB, 305 U.S. 197, 229 (1938). See also 42 U.S.C. §1395ff(b)(1) (explaining appeal rights for suppliers of services); compare 42 U.S.C. § 405(g)

(incorporating the deferential portion of the judicial standard of review contained in the Administrative Procedure Act (APA), as "the court shall review only the question of conformity with such regulations and the validity of such regulations"), and 42 U.S.C. § 139500(f)(1) (incorporating the APA by the Social Security Act that reviewing courts "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law") with 5 U.S.C. § 706(2)(A) (providing that under the APA, courts reviewing agency decisions under the Social Security Act must "hold unlawful and set aside' agency action that is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law""). In this action, the court must review the agency's findings of fact, conclusions, and decisions under a heightened standard of deference because the court is reviewing the agency's interpretation of its own regulations and the applicable statutes, and because of the highly technical nature of the Medicare program. See, e.g., Bowles v. Seminole Rock & Sand Co., 325 U.S. 410, 413-414 (1945) (reasoning that where judicial review involves an interpretation of an administrative regulation a court must defer to the agency's construction of the regulation "if the meaning of the words used is in doubt" and "the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation"); Thomas Jefferson University v. Shalala, 512 U.S. 504, 512 (1994) ("Our task is not to decide which among several competing interpretations best serves the regulatory purpose. Rather, the agency's interpretation must be given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.") (citations omitted).

Here, the language of regulations are plain and not ambiguous, speaks clearly to the precise question at issue, and is not in dispute; but Lifeline challenges the agency's interpretations

of its regulations and its conclusions based on the pleadings and the evidence in the administrative record by alleging that the Secretary committed an error of law when he failed to award additional Medicare reimbursement to Lifeline for its SLS ambulance services. See Bowles, 325 U.S. at 413-414; Thomas Jefferson, 512 U.S. at 512-15; Barnhart v. Walton, 535 U.S. 212, 217-18 (2002) (finding the agency's interpretation of its regulation lawful where the statute did not unambiguously forbid the agency's interpretation and did not exceed the bounds of permissible interpretation). Lifeline is a supplier of ambulance services to Medicare beneficiaries. Therefore, the standard of review is not under the APA, but under the Social Security Act (Act), 42 U.S.C. § 405. See Biron v. Harris, 668 F.2d 259, 260 (6th Cir. 1982).

In this action, because the Appeals Council denied Lifeline's request for review of the ALJ's decision, the ALJ's decision is the final agency decision of the Secretary of the HHS. See 42 U.S.C. §§ 1395ff(b)(1), 405(g). Under the Act, § 405(g) provides that the findings "as to any fact, if supported by substantial evidence, shall be conclusive," and "the court shall review only the question of conformity with such regulations and the validity of such regulations." See also 42 U.S.C. 1395ff(b)(1)(A) (indicating that the "Commissioner of Social Security" as contained in § 405(g) refers to the "Secretary of HHS" in Medicare administrative review actions before that agency); Thomas Jefferson, 512 U.S. at 512; Bowles, 325 U.S. at 413-414; Walton, 535 U.S. at 217-18. Additionally, under the Medicare statutes of the Act the agency must establish regulations for fee schedules for ambulance services and rural area services should be calculated

⁶Therefore, contrary to Lifeline's assertions, neither would Lifeline be entitled to interest on any Medicare payments in connection to its claims even were it to otherwise prevail in this action. See 42 U.S.C. 1395ff (no provisions in statute for interest); see generally, Schweiker v. Chilicky, 487 U.S. 412, 428-29 (1988) (stating only those remedies enumerated in statute are available for claims under the Act).

by locality. 42 U.S.C. §§ 405(a), 1395 et seq.⁷ Pursuant to the Act, the HHS has established its own regulations for payment of ambulance transportation only if certain conditions have been met under the statutes for Medicare reimbursement of ambulance services, see 42 C.F.R. 410.10, 410.40(a), as articulated in its Medicare Carriers Manual.⁸ See A.R. 1, 52-53, 60-61, 219-20, 225-26, 1254.

The ALJ upheld the carrier's and hearing officer's decisions denying Lifeline additional Medicare reimbursement for SLS services. In her decision the ALJ relied upon the Manual §§ 5116, 5200, 5024. Id.; see also Def.'s Mcm. Supp. Summ. J. and in Opp. to Pl.'s Mcm. Supp. Summ. J., Ex. 1, 2. Section 5116 of the Manual states that separate additional charges for specialized ALS services may be permitted where the reasonable total charge does not exceed the all-inclusive base rate. A.R. 60. Specifically, "[a]s with any reasonable charge determination, amounts above the customary and prevailing levels may be allowed when unusual circumstances are documented (§ 5024)." Def.'s Ex. 1, Manual § 5116.6. Section 5024 of the Manual states,

[a] charge which exceeds either the customary charge of the physician or other person who rendered the medical or other health service, or which exceeds the prevailing charge in the locality, or both, may be found to be reasonable. However, this occurs only when there are unusual circumstances or medical complications requiring additional time, effort, or expense which support an additional charge, and only if it is acceptable medical or medical service practice in the locality to make an extra charge in such cases. The mere fact that the physician's or other person's customary charge is higher than the prevailing charge does not of itself

⁷Numerous sub-sections of 42 U.S.C. § 1395 <u>et seq.</u> concern ambulance services which are at issue in this case. <u>See</u> §§ 1395j, 1395l, 1395w, 1395v, 1395x.

⁸During the time period that Lifeline provided the services at issue, from March through August, 1997, Medicare used a retrospective reimbursement plan based on a reasonable charge and all-inclusive payment standard for freestanding suppliers such as Lifeline in Virginia. See 67 FR 9100, 9102 (Feb. 27, 2002); 65 FR 55, 078 (Sept. 12, 2000).

justify a determination of a reasonable charge higher than the prevailing charge.

Def.'s Ex. 2, Manual § 5024 (emphasis added); see also A.R. 60. Under §§ 5024, 5022, "ambulance services are not one of the examples cited" as "certain conditions, such as unusual circumstances or medical complications" that would otherwise warrant "charges higher than customary or prevailing charges." A.R. 60. Additionally, "[i]n Virginia, it is the prevailing practice of ALS providers to bill an all-inclusive base rate' including 'all services provided by the ambulance crew." Id.

The ALJ held pursuant to the Manual §§ 5116, 5022, 5024, that (1) an additional payment to a supplier may be made where it is acceptable medical or medical service practice in the locality of the supplier to make extra charges beyond the ALS all-inclusive base rate for extra personnel, training, and use of new technology for SLS services; (2) it was not the local practice in Virginia to make an extra charge for such reasons above the all-inclusive base rate for ALS services; and (3) nonetheless, Lifeline failed to show the requisite unusual circumstances or medical complications necessary for additional reimbursement above the ALS all-inclusive base rate in Virginia. A.R. 60, 219, 226. Additionally, the ALJ held, inter alia, that Lifeline's compliance with state laws and the EMTALA by being prepared to provide specialized ambulance services as necessary does not rise to the level of unusual circumstances for additional reimbursement because Medicare allows the ALS all-inclusive rate in Virginia to include all services and charges for extra personnel, training, and use of new technology. See id. at 59-61. The record is clear the Lifeline submitted claims and received payment for ALS charges, thereafter it submitted claims for an upward adjustment requesting an additional reimbursement.

<u>Id.</u>; see also Pl.'s Mcm. Supp. Mot. Summ. J., 4. Therefore, as all the administrative reviewers have determined, Lifeline could have included charges for the extra personnel, training, and use of new technology (SLS services) in its all-inclusive base rate if had not already done so when it submitted its ALS charges. <u>See</u> A.R. 19-20, 52-53, 60-61, 225-26, 1254.

Here, the language of the statutes and regulations is not so ambiguous as to provide alternate interpretations by the Sccretary at the time the ALJ's decision became the final agency decision. See Thomas Jefferson, 512 U.S. at 512. Furthermore, the Secretary's decision, incorporating the ALJ's decision as the final agency decision, interpreted the agency's own regulations; therefore the court must give deference to its decisions where its factual findings are supported by substantial evidence. 42 U.S.C. § 405(g). The ALJ's reasoning is consistent with the Medicare statutes, the HHS regulations, and the Manual which incorporates agency regulations. See 42 U.S.C. §§ 405(a), 1395 et seq.; 42 C.F.R. 410.10, 410.40(a); Manual §§ 5116, 5024, 5200. The language in the Manual §§ 5116, 5024, 5200 clearly states that no higher charges above the all-inclusive base rate of the locality, which is Virginia in this case, may be paid unless the provider of services establishes (1) that such charges were reasonable because of unusual circumstances or medical complications, and (2) that it is the practice to do so in the locality. Sec, e.g., A.R. 60. It is not the practice in Virginia to charge above the all-inclusive rate, nor are ambulance services cited in the Manual as an example of unusual circumstances or medical complications. See id. Upon review of the pleadings, administrative record, and all evidence contained therein, it is clear that the Secretary's interpretation of its own regulations simply was not unlawful under the applicable Medicare statutes and was supported by substantial evidence. See Consolo, 383 U.S. at 619-20; Bowles, 325 U.S. at 414; Thomas Jefferson, 512 U.S.

at 512. Therefore, pursuant to Federal Rule of Civil Procedure 56, viewing the facts and inferences to be drawn from those facts in the light most favorable to Lifeline, the court finds that Lifeline fails to show a genuine issue of fact and the Secretary is entitled to judgment as a matter of law. See Matsushita, 475 U.S. at 587-88; Celotex Corp., 477 U.S. at 322.

IV.

For the reasons stated, the court finds that the Secretary's decision to deny additional Medicare reimbursement for SLS ambulance services to Lifeline is not an unlawful interpretation of its regulations. Therefore, the court will grant the Secretary's motion for summary judgment and deny Lifeline's motion for summary judgment. Additionally, because Lifeline will not prevail in this action, the court will also deny its motion for costs and attorney's fees.

ENTER: This /3 day of March, 2006.

SENIOR UNITED STATES DISTRICT JUDGE